EXHIBIT T

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

655 Fifteenth Street, N.W.
Washington, D.C. 20005

Charanjit Brahma
To Call Writer Directly:
202 879-5148
cbrahma@krikland.com

202 879-5000

www.kirkland.com

Facsimile:
202 879-5200

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Via Facsimile and Federal Express

Michael E. Gordon, Esq.
Wilmer Cutler Pickering Hale and Dorr, LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006

Patricia Smink Rogowski, Esq.
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1107 North Orange Street
Wilmington, DE 19801

Re: *Smith Kline & French Laboratories, LTD and SmithKline Beecham Corp., d/b/a GlaxoSmithKline v. Teva Pharmaceuticals USA, Inc.*, Civil Action NO. 05-197 (GMS) (D.Del.)

Dear Mr. Gordon and Ms. Rogowski:

Enclosed please find Defendant Teva Pharmaceuticals USA, Inc.'s Third Supplemental Responses to Plaintiff's First Set of Interrogatories.

Sincerely,

Charanjit Brahma

Enclosures

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES, LTD, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS U.S.A., INC., Defendant.	Civil Action No: 05-197 GMS

DEFENDANT TEVA PHARMACEUTICALS U.S.A., INC.'S THIRD SUPPLEMENTAL RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

Pursuant to Federal Rules of Civil Procedure 26 and 33, Defendant Teva Pharmaceuticals U.S.A., Inc. ("Teva") hereby provides supplemental responses to Plaintiffs' First Set of Interrogatories. Teva reserves the right to further supplement or amend its responses as it obtains additional information during the course of discovery.

GENERAL OBJECTIONS

Teva incorporates each of the objections set forth in its original and supplemental Responses to Plaintiffs' First Set of Interrogatories as if explicitly set forth herein. Those objections are hereby incorporated into each of Teva's supplemental responses as if fully set forth therein.

TEVA'S SECOND SUPPLEMENTAL RESPONSES AND OBJECTIONS

INTERROGATORY NO. 1:
Identify each and every Person who was involved in Teva's decision to file the Teva ANDA and/or to include a Paragraph IV Certification in the Teva ANDA. For each Person, describe with particularity his or her role in the decision(s).

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory to the extent it is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence related to the claims and defenses in this action, in seeking information relating to Teva's decision-making process in filing its ANDA No. 77-460, or in including a Paragraph IV Certification in its ANDA. Teva objects to this Interrogatory to the extent it seeks information relating to Plaintiffs' claim of willful infringement. *See, Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004) ("the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement"). Teva objects to this Interrogatory to the extent it seeks information relating to Teva's decision to include a Paragraph IV Certification as such information is directly protected by the attorney-client privilege. Teva also objects to this Interrogatory as overly broad and unduly burdensome to the extent that it seeks information identifying "each and every Person who was involved" in Teva's decision-making processes, rather than reasonably limiting any such inquiry in number of Persons or in relevant subject matter of any potential "involvement." Teva further objects to this Interrogatory to the extent that it seeks privileged work product and attorney-client communications. Teva objects to this Interrogatory to the extent it purports to be a single interrogatory. Subject to its general and specific objections, Teva supplements its original response as follows.

Teva identifies Deborah Jaskot, Teva's Vice President of Regulatory Affairs as the individual involved in Teva's decision to file Teva's ANDA No. 77-460. Ms. Jaskot is

responsible for overseeing Teva's compliance with FDA regulations, including the submission of Teva's ANDA No. 77-460. In addition, pursuant to Federal Rule of Civil Procedure 33(d), additional individuals, if any, may be derived from the following documents: TEV-RQ 000001-006503. Additional individuals may be identified from any further documents that Teva will produce or make available in response to GSK's requests for production of documents and tangible things. Teva reserves the right to further supplement its response as it obtains additional information during the course of discovery consistent with the Federal Rules, Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware ("Local Rules"), and the Court's Scheduling Order. Teva further identifies each of the witnesses that Teva has made available for deposition by GSK, either in their individual or representative capacity, and incorporates by reference their testimony regarding the identification of individuals who were "involved in Teva's decision to file the Teva ANDA and/or to include a Paragraph IV Certification in the Teva ANDA."

INTERROGATORY NO. 2:
Identify each and every Person who was involved in any way in developing or manufacturing Teva's Proposed Products, including the decision(s) to develop or manufacture Teva's Proposed Products. For each Person, describe with particularity his or her role in the development, manufacture, or decision(s).

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory as overly broad and unduly burdensome to the extent that it seeks information identifying "each and every Person who was involved in any way" in Teva's development, manufacture, or decision-making processes regarding the same, rather than reasonably limiting any such inquiry in number of Persons or in relevant subject matter of any potential "involvement." Teva further objects to this Interrogatory to the extent that it seeks

privileged work product and attorney-client communications. Subject to its general and specific objections, Teva supplements its original response as follows.

Teva identifies Scott Stofik, Deborah Jaskot, and John Kovaleski as individuals involved in the development and manufacture of the drug products identified in Teva's ANDA No. 77-460. Mr. Stofik is a Senior Scientist II in Teva's Generic Research & Development who oversaw the development of the drug products identified in Teva's ANDA No. 77-460. Ms. Jaskot, Teva's Vice President of Regulatory Affairs, and Ms. Capresi, Senior Associate, Regulatory Affairs, both participated in the development of the drug products identified in the ANDA by way of regulatory submissions and/or communications regarding the same. Mr. Kovaleski is Teva's Director of Analytical Research and Development. In addition, pursuant to Federal Rule of Civil Procedure 33(d), additional individuals, if any, may be derived from the following documents: TEV-RQ 000001-006503. Additional individuals may be identified from any further documents that Teva will produce or make available in response to GSK's requests for production of documents and tangible things. Teva reserves the right to further supplement its response as it obtains additional information during the course of discovery consistent with the Federal Rules, Local Rules, and the Court's Scheduling Order. Teva further identifies each of the witnesses that Teva has made available for deposition by GSK, either in their individual or representative capacity, and incorporates by reference their testimony regarding the identification of individuals who were "involved in any way in developing or manufacturing Teva's Proposed Products, including the decision(s) to develop or manufacture Teva's Proposed Products."

INTERROGATORY NO. 3:

State with particularity each and every legal and factual basis for Teva's allegations that the '808 patent is unenforceable or invalid under 35 U.S.C. §§ 101, 102, 103, 112 and 116. The detailed description should include, without limitation, an identification of each statute, judicial or administrative decision, document, tangible item, item of information, piece of prior art, and fact that Teva relied upon in preparing its Answer and Counterclaims, that Teva relied upon in

preparing the Certification Letter or the Teva ANDA, and/or that Teva intends to rely upon as support for its allegations that the '808 patent is unenforceable and/or invalid.

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory as improperly being characterized as one interrogatory because its many subparts constitute separate interrogatories towards the 50 interrogatory limit. *See* D. Del. LR 26.1(b). Teva further objects to this Interrogatory as premature to the extent that it purports to seek expert discovery in advance of the time provided by the Court's Scheduling Order and to the extent that responding to this Interrogatory requires the input of an expert witness(es). Teva reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and Court's Scheduling Order. Furthermore, Teva also expressly reserves the right to supplement its response to this Interrogatory to the extent that Plaintiffs respond with, or are permitted to change or otherwise supplement, their contentions set forth in response to Teva's interrogatories on the issue of patent invalidity. *See, e.g.*, Defendant Teva Pharmaceuticals U.S.A., Inc.'s Interrogatory No. 7 to Plaintiffs GlaxoSmithKline.

Subject to its general and specific objections, Teva responds to the Interrogatory as follows with reference to each individual topic identified in the interrogatory:

(1) Claims 1-5 and 8-12 of the '808 patent are invalid as obvious under 35 U.S.C. §103 in view of the combination of U.S. Patent No. 4,314,944 and at least one of the following references:

(a) Cannon, J.G., Hsu, F., Long, J.P., Flynn, J.R., Costall, B. and Naylor, R.J., "*Preparation and Biological Actions of Some Symmetrically N, N-Disubstituted Dopamines*," J. Med. Chem., 1978, Vol. 21, No. 3: 248-253 ("Cannon 1978 article");

(b) Cannon, J.G., "*Dopamine Congeners Derived from Benzo(f) quinolone Ring*," Advances in Biosciences, 1979, Vol. 20: 87-94 ("Cannon 1979 article");

(c) Cannon, J.G., Demopoulos, B.J., Long, J.P., Flynn J.R. and Sharabi, F.M., "*Proposed Dopaminergic Pharmacophore of Lergotrile, Pergolide, and Related Ergot Alkaloid Derivatives*," J. Med. Chem. - Communications to the Editor, 1981, Vol. 24: 238-240 (1981) ("Cannon 1981 article I");

(d) Cannon, J.G., Long, J.P. and Bhatnagar, R., "*Future Directions in Dopaminergic Nervous System and Dopaminergic Agonists*," J. Med. Chem., 1981, Vol. 24, No. 10: 1113-1118 ("Cannon 1981 article II");

(e) Geissler, H.E., "*3-[2-(Dipropylamino)ethyl]phenol: a new and selective dopaminergic agonist*," Arch. Pharm. (Weinheim) Vol. 310: 749-756 (1977) ("Geissler 1977 article");

(f) Walker, J., Daisley, R.W. and Beckett, A.H., "*Substituted Oxindoles. III. Synthesis and Pharmacology of Some Substituted Oxindoles*," J. Med. Chem., 1970, Vol. 13, No. 5: 983-985 ("Walker 1970 article");

(2) Claims 1, 2 and 6-8 of the '808 patent are invalid under 35 U.S.C. § 101 for failure to show that all of the compounds embraced within the scope of these claims are useful for the purpose intended, and/or under 35 U.S.C. § 112 for failure to describe how to make and use each of the claimed compounds and for failure to satisfy the written description requirement. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article.

(3) Claims 1, 2 and 6-8 of the '808 patent are invalid under 35 U.S.C. § 116 and 256 for failure to correctly join the individual(s) responsible for conceiving of the alleged invention(s) claimed therein and are further invalid under 35 U.S.C. § 102(f) and (g) because the alleged invention(s) claimed therein was invented by another, rather than solely by Mr. Gallagher. During his deposition, Mr. Gallagher admitted that he neither conceived of nor reduced to practice any claimed compound other than ropinirole, yet he is the sole named inventor for the '808 patent. Moreover, Mr. Gallagher was designated as Teva's Rule 30(b)(6) representative concerning "[t]he facts and circumstances regarding the conception and reduction to practice (if any) of the claims of the ['808] Patent[]-in-Suit and the development of the subject matter claimed in United States Patent Nos. 4,452,808 ("the '808 patent") ... from conception up until the time of the filing of the respective applications from which the ['808] Patent[]-in-Suit issued," but, other than to testify that he did not conceive of the entire alleged invention as claimed, Mr. Gallagher was unable to identify the individual(s) who was/were responsible for conceiving of the portions of the claimed invention(s) covering compounds other than ropinirole or its hydrochloride salt. Mr. Gallagher's lack of knowledge should be imputed to GSK. As a result, GSK cannot move to correct the mistaken inventorship of the '808 patent, and the patent is invalid, because GSK cannot identify the other individual(s) responsible for conceiving of portions of the alleged claimed invention(s) covering compounds other than ropinirole or its hydrochloride salt.

(4) Claims 8-12 of the '808 patent are invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation the size of a nontoxic D_2 receptor agonist quantity of each of the claimed compounds upon administration to a human being. A person of ordinary skill in the art would understand that

non-routine testing would be necessary to derive effective, non-toxic human doses from animal testing results. Particularly with respect to claim 11, the specification also fails to teach a person of ordinary skill in the art how to make and use compositions including each of the claimed compounds to as antihypertensive agents. Furthermore, with respect to claim 12, the specification also fails to teach a person of ordinary skill in the art how to make and use compositions including each of the claimed compounds in amounts over the entire recited dose range. Teva intends to rely upon, among other things, Plaintiffs' own dose response and toxicity testing for ropinirole and other compounds in support of this invalidity defense.

(5) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because putative sole inventor Gregory Gallagher admitted that the only compound he conceived of as being useful to treat cardiovascular conditions was 4-(2-di-n-propylaminoethyl)-2(3H)-indolone ("ropinirole") or its hydrochloride salt, and that he neither conceived of using any of the other compounds covered in claim 1 of the patent for the cardiovascular indications identified in the patent specification or for any other purpose nor believed that the compounds of claim 1 shared common structural features such that all of the claimed compounds would exhibit similar physiological effects upon administration. Neither GSK nor Mr. Gallagher can or is willing to identify the individual(s) who conceived of those portions of the alleged invention(s) claimed in the '808 patent that were not conceived by Mr. Gallagher. Yet Mr. Gallagher submitted a sworn declaration to the Patent Office in which he claimed that he had reviewed the claims and specification of the '808 patent application, and that he was the sole inventor of the whole alleged invention(s) claimed therein. At the time he submitted the declaration, Mr. Gallagher knew that his

assertion of sole inventorship was false. Mr. Gallagher's submission of his false inventorship declaration is presumptively material, and in any case, Mr. Gallagher either knew or should have known that his false statements regarding sole inventorship would be material to the patentability of the alleged claimed invention(s). Neither Mr. Gallagher (during his deposition) nor GSK has offered any credible explanation for Mr. Gallagher's knowing submission of a declaration containing false statements regarding inventorship to the Patent Office. Mr. Gallagher submitted his false inventorship declaration to the U.S. Patent & Trademark Office with the intent to deceive the Patent Office and convince the Patent Office to issue the '808 patent.

(6) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification misstates that one of the claimed compounds, ropinirole, was shown to "not cause tachyphylaxis in the [perfused hind limb] preparation as did its 7-hydroxy congener of the prior art" and that this is a proper basis for inferring that the remaining claimed compounds also "may not be subject to tachyphylaxis." Putative sole inventor Gregory Gallagher signed his inventorship declaration stating that he had reviewed the patent specification and that all of the statements in the '808 patent application were true, but at the time he signed that declaration, Mr. Gallagher had not confirmed the accuracy of those statements in the '808 patent specification regarding ropinirole's lack of tachyphylaxis effects. Mr. Gallagher falsely vouched for this statement in the patent specification with the intent to deceive the Patent Office and convince it to accept GSK's assertions in the '808 patent that ropinirole (and the other claimed compounds) had more selective activity and improved physiological characteristics from compounds known in the prior art. Alternatively or in addition thereto, an individual(s) who should have properly

been named as a joint inventor for the '808 patent or who was involved in preparation or prosecution of the '808 patent application knew that the '808 patent specification statements regarding tachyphylaxis were false, and that individual(s) permitted the '808 patent application to be submitted to the Patent Office with the aforementioned false statements with the intent to deceive the Patent Office and convince it to accept GSK's assertions in the '808 patent that ropinirole had more selective activity and improved physiological characteristics from compounds known in the prior art. The submission of these false statements to the Patent Office is inherently material, and the '808 patent specification's statements differentiating the alleged invention(s) claimed in the '808 patent from compounds known in the prior art made these false statements to the Patent Office explicitly material.

(7) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification wrongly suggests that one of the claimed compounds – ropinirole hydrochloride – was tested to determine an effective dose "to show anti-hypertensive activity" in "an average size human." Neither Mr. Gallagher nor GSK has produced any evidence to suggest that any claimed compound – including ropinirole hydrochloride – was tested in humans for anti-hypertensive activity prior to the filing of the '808 patent application, much less that human test results allowed Mr. Gallagher or any person of ordinary skill in the art to determine an effective dose range for treating humans. Indeed, Mr. Gallagher, the putative sole inventor of the alleged invention(s) claimed in the '808 patent, confirmed in his deposition testimony that he only received data from *in vitro* or animal testing of ropinirole or its hydrochloride salt, and that he was not involved in any clinical testing of ropinirole or its hydrochloride salt. The statements in the '808 patent

implying that the disclosed dosage range was effective to cause anti-hypertensive effects in humans by administering ropinirole hydrochloride were materially false. These speculative dose ranges would have been misconstrued by a reasonable Patent Office examiner as supporting the enablement of some or all of the alleged claimed inventions, at least in part. Neither Mr. Gallagher nor GSK has offered any credible explanation why these statements were made in the '808 patent specification or why Mr. Gallagher vouched for their truthfulness in his inventorship declaration. Mr. Gallagher and other individuals involved in the prosecution of the '808 patent intended to deceive the Patent Office by allowing the '808 patent application to be submitted to the Patent Office with these statements suggesting that an effective dose range for ropinirole hydrochloride had been determined.

(8) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because at least one individual who should have been named as a joint inventor with respect to the alleged invention(s) claimed in the '808 patent, J. Paul Hieble, knew of at least one material prior art reference – the Cannon 1981 article I – and had a duty to disclose material prior art references to the Patent Office. The Cannon 1981 article I discloses a structurally similar compound to ropinirole and describes that compound as having both cardiovascular and CNS dopamine-agonist effects when administered in animal models. Rather than disclose that material prior art to the Patent Office, GSK, and, particularly, putative sole inventor Gregory Gallagher, intentionally omitted Mr. Hieble from the list of inventors for the '808 patent with the intent to deceive the Patent Office and prevent the disclosure of material prior art to the Patent Office during the examination of the '808 patent application.

INTERROGATORY NO. 4:

State with particularity each and every legal and factual basis for Teva's allegations that the '860 patent is unenforceable or invalid under 35 U.S, C. §§ 101, 102, 103, 112 and 116. The detailed description should include, without limitation, an identification of each statute, judicial

or administrative decision, document, tangible item, item of information, piece of prior art, and fact that Teva relied upon in preparing its Answer and Counterclaims, that Teva relied upon in preparing the Certification Letter or the Teva ANDA, and/or that Teva intends to rely upon as support for its allegations that the '860 patent is unenforceable and/or invalid.

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory as improperly being characterized as one interrogatory because its many subparts constitute separate interrogatories towards the 50 interrogatory limit. *See* D. Del. LR 26.1(b). Teva notes that no claim terms, phrases, or clauses of the asserted claims have yet been construed by the Court nor have Plaintiffs provided Teva with Plaintiffs' contentions as to the proper construction of any disputed claim terms, phrases, or clauses. Claim construction, which is an issue for the Court, is the first step in an infringement and/or invalidity analysis. Teva further objects to this Interrogatory as premature to the extent that it purports to seek expert discovery in advance of the time provided by the Court's Scheduling Order and to the extent that responding to this Interrogatory requires the input of an expert witness(es). Teva reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and Court's Scheduling Order. Furthermore, Teva also expressly reserves the right to supplement its response to this Interrogatory to the extent that Plaintiffs respond with, or are permitted to change or otherwise supplement, their contentions set forth in response to Teva's interrogatories on the issue of patent invalidity. *See, e.g.*, Defendant Teva Pharmaceuticals U.S.A., Inc.'s Interrogatory No. 7 to Plaintiffs GlaxoSmithKline.

Subject to its general and specific objections, Teva responds to the Interrogatory as follows with reference to each individual topic identified in the interrogatory:

(1) All claims (claims 1-3) of the '860 patent are invalid as having been invented by another. For example, the alleged claimed invention(s) are anticipated under 35 U.S.C. § 102(f) and/or (g) in view of the report entitled "SK&F 101468-A: a centrally acting dopamine agonist having antiparkinson, antidepressant and anxiolytic activity. A neuropharmacological study: Part 1," written by Professors Brenda Costall and R. J. Naylor of the University of Bradford and submitted to Dr. David Owen, the sole "inventor" named on the face of the '860 patent, in September 1986 ("Costall et al. 1986 report"). The Costall et al. 1986 report discloses that ropinirole can be used to treat Parkinson's Disease, specifically stating that "SK&F 101468-A [*i.e.* ropinirole] thus presents a novel dopamine agonist having antiparkinson, antidepressant and anxiolytic potential. ... It would be interesting, therefore, to determine the clinical efficacy of SK&F 101468-A or a related compound in Parkinson's disease ...." (GSK-REQ001062-63.) GSK has presented no documentary evidence, and Dr. Owen was aware of none, to corroborate Dr. Owen's claim that he first arrived at the "hypothesis" that ropinirole could be used to treat Parkinson's disease prior to receiving the Costall et al. 1986 report. Moreover, even if Dr. Owen arrived at his "hypothesis" prior to receiving the Costall et al. 1986 report, that hypothesis was insufficient to constitute conception of the alleged invention(s) claimed in the '860 patent, as it did not evidence a definite and permanent idea that ropinirole could be used to treat human patients with Parkinson's disease. The evidence shows that Dr. Owen was not an inventor, or at least was not the sole inventor, of the alleged claimed invention(s) and that any alleged invention(s) claimed in the '860 patent were actually invented wholly or in part by Professors Brenda Costall and R.J. Naylor of the University of Bradford.

(2) All claims of the '860 patent are invalid as obvious, under 35 U.S.C. §103 in view of the '808 patent and/or '944 patent in combination with at least one of the following references:

(a) the Cannon 1978 article ;

(b) the Cannon 1979 article;

(c) the Cannon 1981 article I;

(d) the Cannon 1981 article II;

(e) Cannon, J.G., "*The Design of Potential Anti-Parkinson Drugs: What is the Dopaminergic Pharmacophore in Ergot Alkaloids?*," Proc. Iowa Acad. Sci. 93(4):169-174, 1986 ("Cannon 1986 article");

(f) the Geissler 1977 article;

(g) Gallagher, Jr., G., Lavanchy, P.G., Wilson, J.W., Hieble, J.P. and DeMarinis, R.M., "*4-[2-(Di-n-propylamino)ethyl]-2(3H)-indolone: A Prejunctional Dopamine Receptor Agonist*," J. Med. Chem. 1985, Vol. 28:1533-1536;

(3) Claim 1 of the '860 patent is invalid under 35 U.S.C. § 101 for failure to show how each of the compounds embraced within the scope of these claims can be administered to a patient suffering from Parkinson's disease to treat that condition and/or under 35 U.S.C. § 112 for failure to describe the alleged invention(s) claimed in the '860 patent and how to practice the claimed method of treating Parkinson's disease by administering each of the claimed compounds. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article, and internal GSK testing of a compound other than ropinirole

that is described one combination of substituents in the general chemical structure recited in claim 1 of the '860 patent showed that this other compound lacked dopaminergic activity.

(4) Claims 1-3 of the '860 patent are also invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation what an "effective non-toxic amount" of a claimed compound that is effective to treat conditions of Parkinson's Disease in a human being. A person of ordinary skill in the art would understand that non-routine testing would be necessary to derive effective, non-toxic human doses from animal testing results. Teva intends to rely upon, among other things, Plaintiffs' own dose response and toxicity testing for ropinirole and other compounds in support of this invalidity defense.

(5) Claim 1 of the '860 patent is also invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation how to administer an "effective non-toxic amount" of any claimed compound other than ropinirole in a manner that is effective to treat conditions of Parkinson's Disease in a human being. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article.

(6) Claim 1 of the '860 patent is invalid under 35 U.S.C. § 116 and/or 256 for failure to properly join all inventor(s) of the entire alleged invention(s) claimed. During his deposition,. Dr. Owen, the putative sole inventor of the '860 patent, admitted that he never even "hypothesized" that any compound other than ropinirole could be used to treat Parkinson's

disease, yet claim 1 of the '860 patent covers many compounds other than ropinirole, much less conceived or reduced to practice the claimed methods of treatment for Parkinson's disease using compounds other than ropinirole or its hydrochloride salt. Moreover, Dr. Owen was designated as Teva's Rule 30(b)(6) representative concerning "[t]he facts and circumstances regarding the conception and reduction to practice (if any) of the claims of the ['860] Patent[]-in-Suit and the development of the subject matter claimed in United States Patent Nos. ... 4,824,860 ("the '860 patent") ... from conception up until the time of the filing of the respective applications from which the ['860] Patent[]-in-Suit issued," but, other than to testify that he did not conceive of the entire alleged invention(s) as claimed, Dr. Owen was unable to identify the individual(s) who was/were responsible for conceiving of the portions of the alleged claimed invention(s) covering the use of compounds other than ropinirole or its hydrochloride salt. Dr. Owen's lack of knowledge should be imputed to GSK. As a result, GSK cannot move to correct the mistaken inventorship of the '860 patent, because GSK cannot identify the other individual(s) responsible for conceiving of portions of the alleged claimed invention(s) covering compounds other than ropinirole or its hydrochloride salt. Furthermore, the evidence of record demonstrates that Professors Costall and Naylor, not Dr. Owen, first conceived of the definite and permanent idea of using ropinirole to treat Parkinson's disease. As a result, the '860 patent is invalid.

(7) The '860 patent and all of the claims therein are unenforceable for inequitable conduct, because putative sole inventor David A.A. Owen admitted that the only compound he conceived of administering to a patient suffering from Parkinson's disease in order to treat that condition was 4-(2-di-n-propylaminoethyl)-2(3H)-indolone ("ropinirole") or its hydrochloride salt, and that he neither conceived of using any of the other compounds

covered in claim 1 of the patent for treating Parkinson's disease nor believed that the compounds of claim 1 shared common structural features such that all of the claimed compounds would exhibit similar effectiveness in treating Parkinson's disease upon administration. Neither GSK nor Dr. Owen can or is willing to identify the individual(s) who conceived of those portions of the alleged invention(s) claimed in the '860 patent that were not conceived by Dr. Owen. Furthermore, Dr. Owen did not even first conceive the alleged claimed invention of using ropinirole or its hydrochloride salt to treat Parkinson's disease, as the idea that ropinirole could be used to treat Parkinson's disease was first proposed in a September 1986 report received by Dr. Owen from Professors Brenda Costall and R.J. Naylor of the University of Bradford. Yet Dr. Owen submitted a sworn declaration to the Patent Office in which he claimed that he had reviewed the claims and specification of the '860 patent application, and that he was the sole inventor of the whole alleged invention(s) claimed therein. At the time he submitted the declaration, Dr. Owen knew that his assertion of sole inventorship was false. Dr. Owen's submission of his false inventorship declaration is presumptively material, and in any case, Dr. Owen either knew or should have known that his false statements regarding sole inventorship would be material to the patentability of the alleged claimed invention(s). Neither Dr. Owen (during his deposition) nor GSK has offered any credible explanation for Dr. Owen's knowing submission of a declaration containing false statements regarding inventorship to the Patent Office. Dr. Owen submitted his false inventorship declaration to the U.S. Patent & Trademark Office with the intent to deceive the Patent Office and convince the Patent Office to issue the '860 patent.

(8) The '860 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification mischaracterizes the prior art bromocriptine compound as a "post-synaptic dopamine agonist." GSK's own researchers – including, for example, in Robert M. DeMarinis, *et al.*, "Syntheses and In-Vitro Evaluation of 4-(2-Aminoethyl)-2(3H)-indolones and Related Compounds as Peripheral Prejunctional Dopamine Receptor Agonists," J. Med. Chem. 29:939-947 (1986) – had previously published articles indicating that bromocriptine was a pre-synaptic dopamine agonist, rather than a post-synaptic dopamine agonist. The '860 patent specification falsely indicates that the anti-Parkinsonian activity of the claimed compounds, including ropinirole, is the result of its post-synaptic, rather than pre-synaptic, site of action, and cites the prior art bromocriptine compound as an example of knowledge among those of ordinary skill in the art that only post-synaptically active dopamine agonists could be used to treat Parkinson's disease. Moreover, Dr. Owen, a co-author of the aforementioned paper by DeMarinis *et al.* did not disclose that material prior art to the Patent Office, which would have allowed the Patent Office examiner to independently discover the false statements in the '860 patent regarding the site of action of the prior art bromocriptine compound. A reasonable Patent Office examiner would have considered the prior art knowledge that bromocriptine acted at a pre-synaptic site of action and the DeMarinis *et al.* paper material to patentability, because the pre-synaptic activity of ropinirole was, as admitted in the '860 patent specification, well-known in the art. The false statement in the '860 patent were brought to the attention of GSK patent attorneys or agents involved in the prosecution of the '860 patent application during its pendency in connection with the prosecution of one of GSK's corresponding foreign patent applications, but neither GSK nor Dr. Owen took steps to correct the false statement in the '860 patent specification.

Accordingly, Dr. Owen and other individuals at GSK involved in the prosecution of the '860 patent application intentionally withheld from the Patent Office information material to the patentability of the alleged invention(s) claimed in the '860 patent and did so with the intent to deceive the Patent Office and convince it to issue the '860 patent.

Date: June 9, 2006

Respectfully submitted,

Josy W. Ingersoll
John W. Shaw
Monte T. Squire
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, Delaware 19899-0391
Telephone: (302) 571-6600

Jay P. Lefkowitz
Edward C. Donovan
Karen M. Robinson
Charanjit Brahma
Corey J. Manley
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200

Attorneys for Defendant Teva Pharmaceuticals U.S.A., Inc.

CERTIFICATE OF SERVICE

I, Charanjit Brahma, counsel for Defendant Teva Pharmaceuticals U.S.A., Inc., caused copies of DEFENDANT TEVA PHARMACEUTICALS U.S.A., INC.'S THIRD SUPPLEMENTAL RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES, to be served, via facsimile and Federal Express, on the date listed below, to:

Patricia Smink Rogowski, Esq. (Bar I.D. 2632)
CONNOLLY BOVE LODGE & HUTZ LLP
The Nemours Building, 1107 North Orange Street
Wilmington, DE 19801
Phone: (302) 658-9141
Fax: (302) 658-5614

Michael E. Gordon, Esq.
WILMER, CUTLER, PICKERING, HALE AND DORR LLP
2445 M Street, NW
Washington, DC 20037
Phone: (202) 663-6000
Fax: (202) 942-8484

Attorneys for Plaintiffs
Smith Kline & French Laboratories, Ltd. and
SmithKline Beecham Corp., d/b/a GlaxoSmithKline

Dated: June 9, 2006